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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/471,146	06/06/1995	MAXIMILIAN GRASSBERGER	900-9523/CON	8226
759	05/24/2002			
ROBERT S HONOR			EXAMINER	
SANDOZ CORPORATION 59 ROUTE 10 E HANOVER, NJ 07936		GOLDBERG, JEROM		JEROME D
		7	ART UNIT	PAPER NUMBER
		<u> </u>	1614	
		Ä	DATE MAILED: 05/24/2002	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
Office Action Summary		08/471,146	GRASSBERGER ET AL.			
	Office Action Summary	Examiner	Art Unit			
	The MAIL INC DATE of this communication and	Jerome D Goldberg	1614			
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status						
1)⊠	Responsive to communication(s) filed on 26 A	pril 2002 .				
2a)⊠	This action is FINAL . 2b) Thi	is action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Dispositi	on of Claims					
,	4) Claim(s) 29-48 is/are pending in the application.					
	4a) Of the above claim(s) is/are withdrav	vn from consideration.				
· · ·	Claim(s) is/are allowed.					
	Claim(s) <u>29-48</u> is/are rejected.					
·	Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.						
	Application Papers					
9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.						
10)	<u> </u>					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
	2. Certified copies of the priority documents have been received in Application No					
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
2) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal F	(PTO-413) Paper No(s) Patent Application (PTO-152)			

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Claims 27-46 have been renumber as claims 29-48.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over the EPA of record, the Johnson '893 patent of record and the Showalter '654 patent of record. EPA describes applicants' compounds on page 32 (compound A), page 98 as Example 21 (compound B), page 95 as part of Example 17 (compound C), page 89 as part of Example 6 (compound D) and page 88 as Example 5 (compound E) as having antimicrobial activity. EPA suggests the use of EPA compound A as an antimicrobial agent to be applied with a "cancer" "external [by]" i.e. topically. The prior art is well aware of how antimicrobial agents are applied topically using lotion, gels and creams. For example, Johnson patent teaches the use of composition for use on skin in the form

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of a lotion, gel or cream (e.g. col. 3, lines 56 though col. 4, line 24). Likewise describing the use of lotions, gels or creams to apply pharmaceutical composition to skin is Showalter patent (col. 16, lines 41-47; col. 40, lines 33-68).

Topical preparations including dusting powders, creams, lotions, gels and spray. These various topical preparations may be formulated by well-known procedures. See for example Remington's Pharmaceutical Sciences, Chapter 43, and 14th Ed. 1970, made Publishing Co. Easton, Pennsylvania 78042, USA. Manifestly, the prior art establishes that a person having ordinary skill in the art wishing to apply the EPA antimicrobial compounds externally to skin would have known to do so by using <u>interalio</u>, lotion, gels or creams.

With regard to the 1% to 3% limitation in the instant claims. EPA is employing a single dosage of 0.5-500mg, which clearly would include a 1720 to 3% amount (see page 77, lines 5-7). Further EPA claim 15 is directed to a pharmaceutical composition.

Applicants' remarks are noted. Applicants state in Paper No. 15, page 7, lines 21-22 that "applicants' agree EPA suggests the use of the compounds as antimicrobials and that it contemplates "external" administration." Applicants further state that the EPA does not contemplate topical administration. On the contrary, EPA explicitly teaches that its compounds may be applied externally to patents. Moreover, the prior art is well aware of how antimicrobial compounds are administered topically in lotions, gels and creams. The prior art, as a whole, contains the necessary incentive, motivation, teachings, suggestion or reason to make applicants' claimed lotions, gels and creams.

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The 35 U.S.C. 112 rejection set forth in paper No. 14 is herein dropped in view of the specific compounds set forth in new claims 29-48. Their compounds have been shown by applicants to be effective.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jermone Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday to Thursday 9 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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308-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Goldberg/LR May 16, 2002

> JEROME D. GOLDBERG PRIMARY EXAMINER